REMARKS

Amendment to the Specification

The specification has been amended to conform to 37 CFR 1.77(b) as requested by the Examiner except that there is no entry under the section heading SEQUENCE LISTING. It is apparent from the subject matter of the application that there would be no sequence listing. However, if the Examiner considers that this section is required, he has authority to add it with the text "Not Applicable".

Acknowledgements of the four prior art references cited in the Office Action, viz. US 6131571 (Lampotang *et al*); EP-A-0745405 (Siemens); EP-A-0861672 (Vladimirovna); & SU-A-1188638 (Dyachenko), have been added to the description of related art.

Amendments have been made to statements of invention for consistency with the claims.

The references to copending PCT applications have been replaced with the relevant application numbers and the publication numbers of the corresponding US applications.

The description with reference to the drawings has been clarified by reference to reference numeral additions to the drawings.

Minor errors have been corrected on pages 12 and 19.

None of the amendments to the specification adds subject matter.

Amendment to the Abstract

The heading to the Abstract has been amended to conform to 37 CFR 1.77(b) and the text amended for consistency with the claims.

Amendment to the Drawing

Figure 1 has been amended to add reference numerals 10 to 13 to indicate the gas inlets and outlet recited in Claim 1; to add suffixes a and b to respective occurrences of reference numerals 102 and 402 to enable the description of the drawing to more clearly identify the high

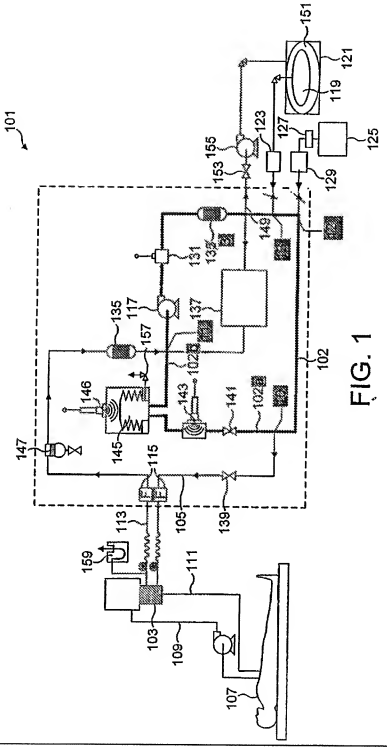
pressure and low pressure sections of the main circuit; to correct the second occurrence of reference numeral 135 to 133; and to correct the reversal of the arrows showing the direction of gas flow from the mass flow controllers (123 & 129) to the main circuit.

Figure 2 has been amended to add reference numeral 208 referred to in the description and for textual identification of the fresh gas supply and spent gas discharge.

Figure 3 has been amended for textual identification of the fresh gas supply and spent gas discharge.

Figure 4 has been amended to add reference numerals 10 to 13 to indicate the gas inlets and outlet recited in Claim 1; to add suffixes a and b to respective occurrences of reference numerals 102 and 402 to enable the description of the drawing to more clearly identify the high pressure and low pressure sections of the main circuit; and to correct reference numerals 237 & 462 to 437 & 460 respectively.

The amendments to reference numerals in the drawings are shown with a shaded background in the following versions of the original drawings


101
102
103
105
107
109
111
113
115
117
119
121
123
125
127
129
131
133
135
137
139
141
143
145
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149
151
153
155
157
159

FIG. 1

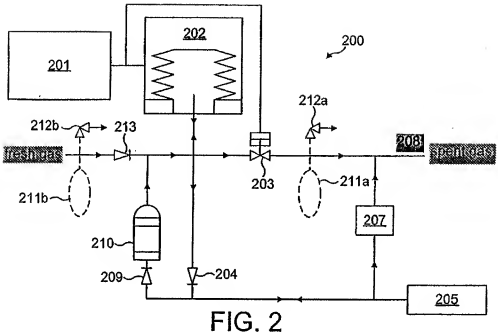

202
200
201
212a
212b
213
208
freshgas
spentgas
203
211a
211b
207
210
209
204
205

FIG. 2

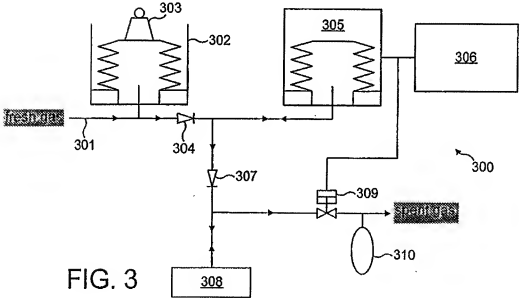
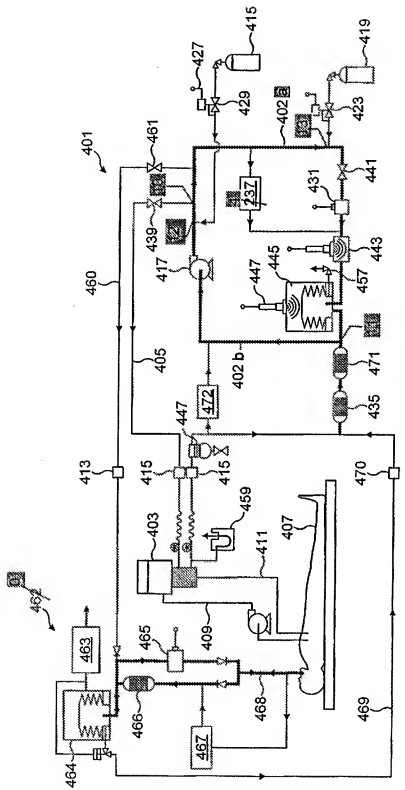

303
305
306
302
freshgas
301
304
307
300
309
spentgas
310
308

FIG. 3


401
402 a
402 b
403
405
407
408
411
413
415
417
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423
427
429
431
435
439
441
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447
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FIG. 4

Amendment to the Claims

Claims 1-24 are pending with Claims 7, 8, 15, 17-23 being withdrawn from consideration. Claims 7, 8, 15, 17-23 are now being cancelled.

Claim 1 has been amended by stating that a constant pressure is maintained in the higher pressure section of the main circuit. There is basis for this amendment at, for example, original page 2, lines 23 to 26 and original page 12, lines 20 to 23.

Claim 1 also has been amended to clarify the identity of the gas inlet referred to in the location of the second feed gas supply inlet and of the feed gas inlet to which the first feed gas supply conduit communicates and to ensure that the relevant terms have antecedence in the claim.

Claim 5 has been amended in response to an objection that was raised in IPER V.2 in connection with the parent application to make it clear that the gains and increases in flow rate are relative to each other.

None of the amendments to the claims adds subject matter.

Election/Restriction

The Examiner has maintained and made final his restriction requirement under 35 USC 121. To this end, Applicants have cancelled Claims 7, 8, 15 and 17 to 23.

The Cited Art

US 6131571 (Lampotang *et al*)

Referring to Figures 1 and 2 thereof, Lampotang *et al* discloses a ventilation and/or anaesthesia delivery system having a recirculation circuit (12) through which gas is circulated by a pump (36). Optionally, means (40; 308) are provided to introduce a liquid anaesthetic for vaporisation immediately downstream of the pump. After passage through a CO_2 absorber (60), bacterial filters (46), an optional heater or cooler (70) and an optional manual breathing bag (92), the gas is delivered at a Y-piece (14) connected to an endotracheal tube (16). The gas pressure at the Y-piece (14) is controlled by a proportional flow control valve (132; 304) downstream of the Y-piece.

The size of an orifice in this valve is varied to alternately create (i) a pressure at the Y-piece that permits flow into the endotracheal tube (16) and (ii) a pressure that permits gas flow from the tube (16) into the circulation loop (12). In order to compensate for variations in gas flow between inhalation and exhalation, a volume reservoir (210; 310) is provided between the proportional control valve and the pump. Make-up gas is supplied via a pair of feed inlet valves (200 and 202) and air can be admitted through an air inlet valve (230). In order to provide for inhalation as well as exhalation, the gas feed to the pump (36) is at subatmospheric pressure.

EP-A-0745405 (Siemens)

Siemens discloses an anaesthetic system in which a breathing circuit can be switched between an open system and a rebreathing system. In the rebreathing system, a pressure-transfer unit applies rhythmic pressure changes to control the breathing of the patient. In the exemplified embodiment, the pressure-transfer unit is a bag and bottle as conventionally used in the anaesthetic art.

EP-A-0861672 (Vladimirovna)

Vladimirovna was cited in the ISA (as D2) and applied in the Written Opinion and IPER of the parent PCT application (PCT/GB03/01875). It discloses an inhalation apparatus having a recirculation circuit comprising a breathing bag (5), gas flow inducer (9); oxygen gas analyser (14); carbon dioxide gas analyser (15); temperature controller (10); gas flow switch (24); and absorbent filters (12, 11). The gas flow switch provides for open cycle operation. Gas is supplied to a face mask (19) by a gas inlet conduit (20) controlled by an inhalation valve (17). Exhaled gas is returned to the recirculation circuit downstream of the inlet conduit (20) via a microflora-removing device (25) and an exhalation valve (18). A non-return valve (26) is provided in the recirculation circuit between the inlet and outlet to the mask (19) to prevent reversible of gas flow. Make-up gas is supplied by an inlet conduit (6) upstream of the breathing bag (5). The concentration of oxygen in the recirculated gas is controlled by a valve (7) responsive to signals from the gas analysers (14, 15). The gas flow inducer (9) is stated to *reduce gasodynamic inhalation resistance by increasing the gas pressure* but no other details of the operation or construction of the inducer (9) are provided. Additional components are introduced into the feed conduit (6) from respective containers (3) via respective valves (4) but no detail of operation of these valves is provided.

SU-A-1188638 (Dyachenko)

Dyachenko discloses the use ultrasonics to detect changes in gas composition but otherwise has no relevance to the present application.

Claim Rejections under 35 USC § 102

With respect, the Examiner's assertion that apparatus within the scope of Claims 1 and 3 to 6 and the method of Claim 16 are anticipated by Lampotang *et al* is mistaken.

The delivery system of Lampotang *et al* is fundamentally different from that of the present invention in that considerable pressure variation is required in the circulation loop (12) of Lampotang *et al* in order to provide for inhalation and exhalation at the Y-piece (14). In contrast, the apparatus of the present invention maintains constant pressure and gas flow at the feed to the medical device.

In terms of the requirements of present Claim 1, the delivery system of Lampotang *et al* does not have at least the following features:

- pressure maintaining valve dividing the circulation loop into a higher pressure section and a lower pressure section,
- spent gas inlet in a different (lower) pressure section from the medical gas outlet (in the higher pressure section),
- concentration determining means measuring the concentration of at least one component of the recirculating gas mixture;
- two separate ("first" & "second") feed gas flow control means of which one is responsive to a signal from concentration determining means and the other is responsive to a signal from circuit volume regulating means, and
- purification means in the medical device supply circuit for removing contaminants from the spent gas.

In connection with the above, the proportional flow control valve (132) of Lampotang *et al* does **not** constitute a pressure-maintaining valve dividing the main circuit into a higher pressure section and a lower pressure section. As explained at Lampotang *et al* column 19, lines 49/65, the proportional flow control valve provides alternating back pressure and suction at the Y-piece (14) providing ventilation to the patient. The delivery system of Lampotang *et al* could not operate if the proportional flow control valve was replaced by a pressure maintaining valve.

Further, the multi-gas analyzer (120) Lampotang *et al* does **not** measure the concentration of any component of the **recirculating** medical gas mixture. As explained at Lampotang *et al* column 13, lines 25/33, the sampling port for the analyzer is specifically located at the distal tip (32) of the endotracheal tube (16) and not at the Y-piece 14 so as to **avoid** analyzing gas in the main gas circuit (12).

Lampotang *et al* does **not** disclose controlling the "first" feed control valve (200) in response to a signal from the multi-gas analyzer (120) and the "second" feed gas control valve (202) in response to a signal from the bellows (212). The description in Lampotang *et al* of the operation of those valves clearly states that they are both responsive to signals from the multi-gas analyzer (see column 21, lines 9/14) and from the bellows (see column 21, lines 38/43). Moreover, as mentioned above, the multi-gas analyzer specifically does **not** analyze the **recirculating** gas.

There is no flow control means in the Y-piece or the endotracheal tube (16) Lampotang *et al*. Even if the limb of the Y-piece to which the endotracheal tube is attached can be considered as constituting a supply circuit to that tube (*arguendo*), there is no provision in that limb for controlling the flow of gas through it. That gas flow is controlled by the proportional control valve (132), the breathing bag (94) and the purge valve (130).

Claim Rejections under 35 USC § 103(a)

It is respectfully submitted that the amended claims are patentable over the prior art and, in particular, that the claimed subject matter is not obvious over Lampotang *et al* whether considered alone or in view of any one or combination of Siemens, Vladimirovna and Dyachenko.

The problem to which the present invention is directed is to recirculate spent gas from a medical device in a manner that ensures that the feed to the medical device is maintained at constant pressure and constant composition. In its broadest aspect (as defined in Claim 16), the solution is to divide the recirculatory circuit into higher and lower pressure sections, to maintain the gas composition by replenishing components and to take the feed to the medical device from the higher pressure section and to return the spent gas to the lower pressure section. None of the cited references is directed to this problem. In particular Lampotang *et al* is concerned with a ventilator and/or anaesthesia delivery system that relies upon pressure variation at a location in the

recirculatory circuit to alternately provide and remove a gas mixture from a patient's lung.

In order to derive the present invention from Lampotang *et al*, it is necessary for the skilled person to first make the decision that the teaching of Lampotang *et al* could have any relevance to provision of gas to a medical device at a **constant** pressure. It is an essential feature of Lampotang *et al* that variations in pressure in the recirculatory circuit should provide the motive force to provide ventilation to a patient and there is no teaching in Lampotang *et al* that the circuit might be used for any other purpose. If the skilled person did decide to modify Lampotang *et al* to provide a constant pressure at the feed location (14) to the endotracheal tube (16) (*arguendo*), there is no reason to believe that it would be considered necessary to retain either the flow control valve (132) or the bellows (218), because both of these components are present in order to facilitate the flowrate waveform required for patient ventilation.

With particular reference to the rejection of Claim 2 as being obvious over Lampotang *et al* in view of Simians, the differences between Lampotang *et al* and the present invention are so substantial that it is apparent that no combination with the teaching of Siemens that could not have led the skilled person to devise the apparatus of Claim 2 from the disclosure of Lampotang *et al*. The apparatus for that claim incorporates all of the features of Claim 1 and additionally the requirement that the feed gas supply inlets are located in the higher pressure section. Regardless of whether or not it was known in the art that feed gas supply inlets are located in the higher pressure section of a dual pressure main gas circuit, the apparatus Claim 1 would remain inventive over the prior art because of the combination of features required by that claim.

With particular reference to the rejection of Claim 9 as being obvious over Lampotang *et al* in view of in view of Dyachenko, the fact that it was known to use ultrasonics to detect changes in gas composition does not render Claim 3 obvious because, as in the case of Claim 2, it incorporates the novel and inventive combination of the apparatus of Claim 1.

With particular reference to the rejection of Claims 12 and 13 as being obvious over Lampotang in view of Vladimirovna, there is no reason for the teaching of Vladimirovna to be combined with that of Lampotang *et al*. Vladimirovna is not concerned with ventilation and/or anaesthesia delivery but merely with the provision of a breathing mixture to a face mask. There may be individual features of Vladimirovna that might possibly be incorporated into the system of

Lampotang but they would not directly concern the recirculatory circuit because of the essential requirement of Lampotang *et al* that there is pressure variation to provide feed to and discharge from the endotracheal tube (16).

In connection with Vladimirovna, it should be noted that it appears that the recirculatory circuit in Vladimirovna does not have the high pressure and low pressure section required by the present claims and that the pressure in the recirculatory circuit at which the fresh gas is removed for feeding to the face mask is substantially the same as that at which the spent gas is returned from the face mask. The valve (26) between the feed and return locations is merely a one-way valve to prevent back flow of spent gas.

Objections relating to 37 CFR 1.77b

The objections under 37 CFR 1.77b have been resolved by amendment of the specification and abstract. As mentioned above, if the Examiner wants to add a Sequence Listing section, he can do so subject to the section text being "Not Applicable"

Summary

In view of the amendments and remarks above, the Applicant request that the objections rejections set forth in the Office Action mailed on 19 February 2010 should be reconsidered and withdrawn. A timely Notice of Allowance is requested for the amended claims.

Respectfully submitted,

Willard Jones, II
Registration No. 31,172
Air Products and Chemicals, Inc.
Allentown, Pennsylvania 18195-1501
(610) 481-4587